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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,936	12/22/1998	Scott Miller	BAYER 6 P1	8682

7590

11/02/2004

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EXAMINER

KUMAR, SHAILENDRA

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/776,936

Applicant(s)

MILLER ET AL.

Examiner

SHAIENDRA - KUMAR

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 and 14 is/are allowed.
- 6) ☒ Claim(s) 1, 3-11, 13 and 15-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

This office action is in response to applicants' communication filed on 10/8/2004.

The FINALITY of the office action is hereby withdrawn and the following office action is in order.

Claims 1 and 3-27 are pending in this application.

Claim Rejections - 35 USC § 112

1. Claims 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not give any guidance as to the method of treating cancerous cell growth using the compounds of the instant claims. In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described. They are:

- 1) Nature of the invention
- 2) The state of the prior art,
- 3) The predictability or lack thereof in the art,
- 4) The amount of direction or guidance present,
- 5) The presence or absence of working example,
- 6) The breadth of the claims,

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7) The quantity of the experimentation needed, and

8) The level of the skill in the art.

Nature of the invention: claims 15-19 are directed to method of treating cancerous cell growth mediated by raf kinase, comprising administering the claimed compounds. It is understood that the treatment includes humans as well.

The state of the prior art: while the state of the art is relatively high with regard to the treatment of cancerous cell growth, the state of the art with regard to a single agent for treating cancer broadly is underdeveloped. In particular, there is no known anticancer agent, which is effective against cancer such as pancreatic, lung and colon, thyroid or bladder for that matter.

The predictability or lack thereof in the art: The lack of significant guidance from the specification or prior art with regard to the actual treatment solid cancers in human subject with the claimed compounds makes practicing the claimed invention unpredictable.

The amount of direction or guidance present: The guidance given by the specification as to how to treat the solid tumor I limited the discussion of the literature only, and various citations have been provided with respect to the corrlationship of in vivo and in vitro inhibition growth with respect to the inhibition of ras kinase. However, the compounds of the claimed subject matter are vastly different than the cited prior art. The guidance provided in the instant specification is as to how to do the assay per the prior art, without substantiating any experimental evidence.

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The presence or absence of working examples: All the examples provided in the specification are only drawn to as to how to make the compounds. There is not a single example provided which can point out to the treatment of the solid tumor.

The breadth of the claims: The complex nature of the claims greatly exacerbated by breath of the claims. The claims encompass treating cancerous cell growth mediated by raf kinase broadly.

The quantity of the experimentation needed: Applicants have failed to provide guidance and information to allow the skilled artisan to ascertain which particular type of cancer the claimed anticancer agent is effective against. Applicants have even failed to provide any in vitro data, which can be extrapolated to the in vivo data. Instant claimed compounds are drawn to at least millions of compounds and applicants have not provided as to which will inhibit ras kinase and in turn which compound can be used to treat what type of the cancer.

The level of the skill in the art: The level of ordinary skill in the art treating the cancerous cell growth is considered to be relatively high. Those responsible for formulating the compositions would be individuals with MS or PhD or MD credentials, or minimally 8-10 years of actual hands on experience.

Claim Rejections - 35 USC § 103

2. Claims 1, 3-11, 13, and 20-27 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Widdowson(WO'157),for the reasons of record.

Applicants argue that the reference on page 20 last two lines suggest the pKa to be less than 10 as against greater than 10 claimed herein. At the outset, neither the reference nor in the instant specification there is any data that suggest the pKa value of any compound whatsoever. The Table I in the instant specification fails to list

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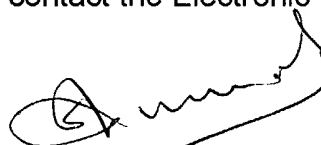
any compound with the required pKa limitation. Inasmuch as the substituents are overlapping, the pKa values are supposed to overlap too, absent evidence to the contrary.

3. Claims 12 and 14 are free of prior art and are allowable.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA - KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAILENDRA - KUMAR
Primary Examiner
Art Unit 1621

S.Kumar
10/25/04